

**REMARKS**

This Amendment rewrites claim 8. The biodegradable feature of claim 8 is supported by page 13, lines 6-7 ("during the dissolution of the matrix"). Claims 8-16 are pending.

This Amendment overcomes the 35 U.S.C. § 112, second paragraph, rejection of claims 8-16. More particularly, claim 8 has been rewritten by deleting "that". One of ordinary skill in the art will easily understand that the claimed composition is obtained by first preparing a sol from a tetraalkoxysilane (together with other reagents), and then subjecting the sol to hydrolysis, during which time the tetraalkoxysilane is co-hydrolyzed with an organomodified alkoxysilane. Part of the tetraalkoxysilane is thus replaced by the organomodified alkoxysilane, as illustrated by the Example on page 7. Reconsideration and withdrawal of the indefiniteness rejection of claims 8-16 are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 8-16 over U.S. Patent No. 5,858,280 to Zhang et al. in view of U.S. Patent No. 5,804,318 to Pinchuk et al. is respectfully traversed. The inventors have discovered a composition comprising a silica xerogel which is capable of controlled release of a biologically active agent, and its method of preparation.

The cited combination of references fails to raise a prima facie case of obviousness against the claimed composition and method. Zhang et al. fails to disclose or suggest that its composition could be used for the controlled release of a biologically active agent. Instead, Zhang et al. teaches a transparent silica gel, useful as a host material for doping optically functional molecules. The gel can be used, for example, in magnetic recording media (Col. 5, lines 1-2). The gel is prepared by reacting methyltrialkoxysilane, and optionally other silanes, in the presence of a catalytically effective amount of a metal complex. See claim 1. This metal complex is described as critical (Col. 3, lines 39-40). The metals of Groups 2-13 of the periodic chart and alkali metals may be used (Col. 3, lines 50-52). These compounds appear unsuitable for medical use.

It is respectfully noted that there is no evidence of record to support the Patent Office argument that one of ordinary skill in the art would understand from the size of space defined by the Zhang et al. polysiloxane network that it would be suitable as a carrier for biologically active agents.

Pinchuk et al. also fails to disclose or suggest the claimed composition. Instead, Pinchuk et al. discloses a surface coating comprising a hydrogel containing pendant amine groups (Col. 3, lines 26-29). The hydrogel is adhered to a surface to be coated by

using, for example, a silane priming or coupling agent (Col. 4, line 27). The silane agent is therefore to be used only for silylation of the surface of the material to be coated, and thus the coating itself is not made of sol-gel derived silica xerogel derived from tetraalkoxysilane, as in the present invention. This is evident from Col. 5, lines 13-15, which teach that the quaternary ammonium cation-containing surface is rendered non-thrombogenic.

In short, Pinchuk et al. fails to disclose or suggest heparin is released from its hydrogel. The reference fails to disclose or suggest that an anti-thromogenic agent such as heparin can be encapsulated into sol-gel derived xerogel derived from tetraalkoxysilane which has been co-hydrolyzed with an organomodified alkoxysilane, or that heparin may be controllably released from the xerogel.

Reconsideration and withdrawal of the obviousness rejection of claims 8-16 over Zhang et al. in view of Pinchuk et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 8-11 over Kuncova et al., 60 Collect.Czech.Chem.Comm. 1573 (1995) in view of Pinchuk et al. is respectfully traversed. The inventors have discovered a composition comprising a silica xerogel which is capable of controlled release of a biologically active agent.

The cited combination of references fails to raise a prima facie case of obviousness against the claimed composition. Although Kuncova et al. discloses a modification of conventional sol-gel procedures by co-hydrolysis of silicon alkoxides with (3-thiopropyl)trimethoxysilane and (3-aminopropyl)triethoxysilane, the reference teaches the immobilization of a biologically active material (lipase). One of ordinary skill in the art is given no suggestion that a xerogel obtained from co-hydrolysis of an organomodified alkoxysilane and an alkoxysilane may be used to controllably release a biologically active agent such as heparin.

Pinchuk et al. also fails to disclose or suggest that a biologically active agent such as heparin can be encapsulated into sol-gel derived xerogel derived from tetraalkoxysilane which has been co-hydrolyzed with an organomodified alkoxysilane, or that heparin may be controllably released from such a xerogel.

Reconsideration and withdrawal of the obviousness rejection of claims 8-11 over Kuncova et al. in view of Pinchuk et al. is respectfully requested.

It is believed the application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 8-16, and issuance of a Notice of Allowance directed to those claims, are earnestly requested. The Examiner is urged to telephone the

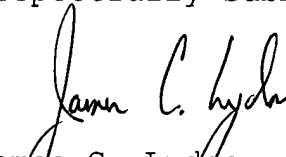
U.S. Patent Appln. S.N. 10/069,145  
AMENDMENT

**PATENT**

undersigned should she believe any further action is required for allowance.

It is not believed that any fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is authorized to charge our Deposit Account No. 50-1258 in the amount of any such fee deemed necessary for such entry and consideration.

Respectfully submitted,



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